EMA/664633/2016
EMEA/V/C/004201

EPAR summary for the public

Halagon

halofuginone

This is a summary of the European public assessment report (EPAR) for Halagon. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Halagon.

For practical information about using Halagon, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Halagon and what is it used for?

Halagon is a medicine used to treat newborn calves to prevent or reduce diarrhoea caused by an organism called *Cryptosporidium parvum*. This is a parasite belonging to the 'protozoa' family that invades the digestive system, causing diarrhoea. The infection is known as cryptosporidiosis.

The medicine contains the active substance halofuginone.

Halagon is a 'generic medicine'. This means that Halagon is similar to a 'reference medicine' already authorised in the EU called Halocur.

How is Halagon used?

Halagon can only be obtained with a prescription and is available as an oral solution (liquid to be given by mouth). It is given to newborn calves once a day for one week. For prevention of diarrhoea, treatment should start within 24 to 48 hours of birth; for reducing diarrhoea, treatment should start within 24 hours of the start of diarrhoea. Halagon should be given after feeding.

For further information, see the package leaflet.

How does Halagon work?

The active substance in Halagon, halofuginone, prevents the growth of *Cryptosporidium parvum*. It also limits the spread of the disease by preventing the formation of oocysts, which are a stage in the lifecycle of the parasite that are passed in the faeces. The exact way halofuginone works is unknown.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

How has Halagon been studied?

The company provided data on the quality and manufacture of Halagon. No additional studies were needed as Halagon is a water based oral solution containing the same active substance and other ingredients as the reference medicine, in the same concentrations.

What are the benefits and risks of Halagon?

Because Halagon is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Safety information has been included in the summary of product characteristics and the package leaflet for Halagon, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers when using Halagon. Because Halagon is a generic medicine and is bioequivalent to the reference medicine the precautions are the same as for the reference medicine.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption.

The withdrawal period for meat from newborn calves treated with Halagon is 13 days.

Why is Halagon approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that, in accordance with EU requirements, Halagon has been shown to have comparable quality to Halocur. Therefore, the CVMP's view was that, as for Halocur, the benefits outweigh the identified risks. The Committee recommended that Halagon be approved for use in the EU.

Other information about Halagon?

The European Commission granted a marketing authorisation valid throughout the EU for Halagon on 13 December 2016.

The full EPAR for Halagon can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Halagon, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in October 2016.